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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,139	04/05/2007	Don Channer	CUL/0023	4875

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EXAMINER	
DOUGHERTY, SEAN PATRICK	
ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
11/12/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/587,139	CHANNER ET AL.	
	Examiner	Art Unit	
	SEAN P. DOUGHERTY	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the FINAL Office action based on the 10/587139 application filed April 5, 2007. Claims 1-9, 11 and 12, as filed, are currently pending and have been considered below.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 23, 2008 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites a pistons that comprises at least two fingers members, however, in claim 5, it is recited that the two finger members are on the piston. Examiner notes that the limitations "comprises" and "on" make it unclear if the two fingers members are

on the piston or not, because the limitation for the piston to comprise two finger members does not necessarily mean that the two finger members are "on" the piston. For examination purposes, Examiner has interpreted claims 4-7 as if the two fingers members are located on the piston.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated US 6,186,960 to Tripp et al. (Tripp).

Re claims 1 and 9, Tripp discloses a housing 12 having an open rear end 34 adapted to accommodate an evacuated blood collecting tube (col. 3, lines 5-10) and a front end 32, a needle holder 14 in the front end 32, a needle 48 which is attached to the needle holder 14 and which is double ended (col. 3, line 2) and has a first end (outer end) that projects from the housing and a second end (inner end) that projects into the housing (col. 3, lines 3-6), the needle holder being releasably attached relative to the housing (col. 2 lines 61-63) to enable the needle holder and the attached needle to be retracted (col. 3 lines 56-60), and a needle retraction device 18, the needle retraction device able to be pushed into the housing (abstract, lines 15-16) to release the needle

holder from the housing and to retract the needle holder containing the attached needle into the needle retraction device (col. 3 lines 56-60), wherein the needle holder contains at least two finger members 16 that engage relative to the housing to retain the needle holder to the housing, each finger member 16 being deflectable between a locking position (see Fig. 5) where the finger member retains the needle holder to the housing (col. 2, lines 61-65), and a release position (see Fig. 7) where the needle holder can be retracted into the housing (col. 3, lines 53-55).

Re claim 2, Tripp discloses a needle holder comprising an assembly of at least two parts, the first part being an inner part 46 and containing a passageway through which a puncture needle can extend to fit the puncture needle to the inner part (note that Fig. 2 discloses a puncture needle 48 extending to fit to an inner part 46), the second part comprising an outer nosepiece 44, the at least two finger members being attached relative to the nosepiece (note that Fig. 2 discloses the finger members 16 attached relative to an outer nosepiece 44).

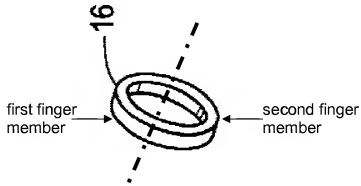
Re claim 3, Tripp discloses a needle retraction device comprising an elongate hollow body 30 which contains a vacuum 70 (col. 5, line 34; col. 3, lines 22-24) and which has an open end 62, a piston 20 which closes off the open end of the elongate hollow body and which is adapted for sliding movement within the hollow body, and which is releasably attached relative to the open end (col. 6, lines 36-37).

Re claim 4, Tripp discloses where the piston comprises at least two finger members 24/28 which releasably attach the piston relative to the one end of the hollow body, each finger member of the piston being movable between a locking position (see

Fig. 5) where the piston is attached to the hollow body (col. 3, lines 43-46), and a release position (see Fig. 7) where the piston can be retracted into the hollow body under the influence of the vacuum (col. 3, lines 51-60).

Re claim 5, Tripp discloses the at least two finger members on the piston extend forwardly from the piston (note that the at least two finger members 24/28 are on the distal end of the piston, thus extending forwardly), and the at least two finger members on the needle holder extend rearwardly (note that the at least two finger members 16 are proximal front end 32, thus extending rewardly) such that as the needle retraction device is pushed against the rear of the needle holder (abstract, lines 15-16), the at least one finger member on the piston releases the at least one finger member on the needle holder, and engages to the at least one finger member on the needle holder (col. 3, lines 43-50).

Re claims 11 and 12, note that Tripp discloses the at least two finger members that are radially spaced about the needle holder. Tripp establishes a ring containing two finger members, each of the finger members radially spaced from each other around the ring (see diagram below).



Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over US Tripp, as applied to claim 5, in view of US 5,000,736 to Kaufhold et al. (Kaufhold).

Re claim 6, Tripp discloses a housing 12, the housing contacting the at least one finger member on the piston (col. 3, lines 40-43; the Examiner notes Fig. 6 discloses the one finger member in contact with the housing) when the needle retraction device is pushed against the rear of the needle holder (abstract, lines 15-16), the at least one finger member releases the at least one finger member from engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum (col. 3, lines 43-50).Tripp does not appear to disclose where the housing is provided a ramp in a forward portion of the housing, the ramp contacting the at least one finger member on the piston when the needle retraction device is pushed against the rear of the needle holder, the at least one finger member riding along the ramp to release the at least one finger member from engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum. However, Kaufhold teaches a housing is provided a ramp (taper d, Fig. 7) in a forward portion of the housing, the ramp contacting the at least one finger member on the piston when the needle retraction device is pushed against the rear of the needle holder, the at least one

finger member riding along the ramp to release the at least one finger member from engagement with the hollow body to enable the piston containing the attached needle holder to be retracted into the hollow body under the influence of vacuum.

Tripp and Kaufhold are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp and Kaufhold before him or her to modify the housing of Tripp to include the ramp Kaufhold. The Examiner notes that this is simple substitution of the housing of Tripp to include the ramp of Kaufhold to obtain the predictable result of the at least one finger on the piston to ride along the ramp to release the at least one finger member from the engagement with the hollow body to enable the piston to retract into the hollow body. The Examiner notes that the finger as disclosed in Tripp already rides along the housing of Tripp to engage and release the piston into the hollow body; adding the ramp as taught in Kaufhold simply modifies the housing of Tripp, obtaining the same result of the release of the piston into the hollow body. The suggestion/motivation for doing so would have been to "provide a disposable medical collection tube holder with retractable needle" (col. 3, lines 65-67) as disclosed by Tripp, to "provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory" (col. 4, lines 1-4) as also disclosed by Tripp and to "provid[e] a means of automatically, without the need of unusual manipulation,

rendering a used syringe safe for handling immediately after use" (col. 1, lines 65-67) as taught by Kaufhold.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Tripp and Kaufhold as applied to claim 6, further in view of US 6,572,565 to Daley et al. (Daley).

Re claim 7, Tripp discloses a piston 20 and a needle retraction device 18 that are pushed against the rear of the needle holder (abstract, lines 15-16). Tripp does not appear to disclose where the piston contains a pierceable material that is pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end of the needle. However, Daley teaches a piston that contains a pierceable material that is pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end of the needle (col. 5, lines 31-34; note that Fig. 2 discloses the inner end of the needle 30 sealed by the pierceable material 66).

Tripp and Daley et al. are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp and Daley before him or her to modify the piston of Tripp to include the pierceable material of Daley. At the time of the invention, it would have been obvious to one of ordinary skill in the art, to modify the piston disclosed by Tripp by adding the pierceable member taught by Daley to be

pierced by the inner end of the needle when the needle retraction device is pushed against the rear of the needle holder to seal the inner end of the needle. The suggestion/motivation for doing so would have been to "provide a disposable medical collection tube holder with retractable needle" (col. 3, lines 65-67) as disclosed by Tripp, to "provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory" (col. 4, lines 1-4) as also disclosed by Tripp and to "provide an improved blood sampling assembly for retracting a needle and needle seat from a cylinder and thereby shielding the needle after completion of a blood collection procedure" (col. 3, lines 44-47) as taught by Daley.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Tripp, Kaufhold and Daley as applied to claim 7, further in view of US 5,352,203 to Vallenlunga et al. (Vallenlunga).

Reclaim 8, Tripp discloses a piston 20 that retracts into a hollow body (col. 6, lines 36-37). Tripp does not appear to disclose where the piston contains a speed controller to control a speed of retraction of the piston into the hollow body, the speed controller comprising a sealing member extending from the piston and sealingly engaging with the hollow body to increase the frictional force of the piston on the hollow body. However, Vallenlunga where a piston contains a speed controller to control a speed of retraction of the piston into the hollow body, the speed controller comprising a

sealing member extending from the piston and sealingly engaging with the hollow body to increase the frictional force of the piston on the hollow body (col. 4, lines 10-14).

Tripp and Vallenlunga are analogous art because they are from the same field of endeavor/problem solving area of disposable medical collection tube holder assemblies with retractable needles. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Tripp and Vallenlunga before him or her to modify the plunger of Tripp to include the sealing members extending from the piston and sealing engaging with the hollow body providing a friction force of Vallenlunga. At the time of the invention, it would have been obvious to one of ordinary skill in the art, to modify the plunger to include sealing members along the walls to provide friction. It is known to one of ordinary skill in the art that a plurality of protrusions along the plunger to form a friction fit with an inner diameter would obtain the predictable result of creating friction acting as a speed controller. The suggestion/motivation for doing so would have been to "provide a disposable medical collection tube holder with retractable needle" (col. 3, lines 65-67) as disclosed by Tripp, to "provide a disposable medical collection tube holder with retractable needle that allows safe disposal of used needles when used with a companion evacuated accessory" (col. 4, lines 1-4) as also disclosed by Tripp and to a "plunger for a non-reusable syringe ... capable of aspirating fluids" (col. 1, lines 5-9) and to provide "a non-reuseable syringe which becomes inoperative or incapable of further use automatically without an additional act on the part of the user" (col. 1, lines 42-45) as disclosed by Vallenlunga.

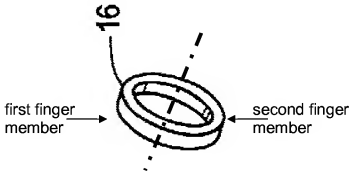
Response to Amendment

Examiner acknowledges amended claims 1, 2, 4-6, 9, new claims 11 and 12 and cancelled claim 10 in the amendments filed September 23, 2008.

Response to Arguments

Applicant's arguments filed September 23, 2008 have been fully considered but they are not persuasive.

Applicant argues that Tripp does not disclose a needle holder which contains at least two finger members that engage relative to the housing to retain the needle holder to the housing. Examiner disagrees and respectfully submits that the hub release ring of Tripp establishes two finger members as shown below:



Each side of the hub release ring is required for the ring to properly function, thus establishing two finger members to create the hub release ring. The hub release ring is analogous to two finger members and there is nothing to prevent one from interpreting the hub release ring as containing two finger members.

Applicant further argues that the hub release ring of Tripp is not deflectable between varying positions. Examiner disagrees and respectfully submits that the hub

release ring is deflectable between a retaining position as best seen in Fig. 5 and a release position as best seen in Fig. 7.

Examiner contends that Tripp discloses at least two finger members, and the finger members are deflectable between varying positions, thus the rejections as presented stand.

Conclusion

This is a request for continued examination under 37 CFR 1.114 of applicant's earlier Application No. 10/587139. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Friday, 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736